REMARKS

Status of the Claims

The Office Action of October 24, 2005 has been received and considered. Claims 1-32 were originally pending. Claims 4-13 and 19-32 have been canceled due to a restriction requirement. Claims 1-3, and 14-18 remain pending. Reconsideration of the application in view of the amendment and following remarks is requested.

Election of Invention

The applicant hereby affirms the rejoinder of Groups IV and I and the election of claims 1-3 and 14-18.

The Rejections of Claims 1-3 and 14-18 Under 35 U.S.C. §112, Second Paragraph Should be Withdrawn:

Claims 1-3 and 14-18 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. This rejection is respectfully traversed.

Claims 1 and 4 were rejected by the Examiner as being vague and indefinite for recitation of "examining said collected material". The Applicants respectfully disagree with the Examiner that the term "examining said collected material" is vague and indefinite. The Applicant has provided numerous examples of ways by which one of ordinary skilled in the art may examine the collected material. For instance, on page 5, lines 1-4, of the specification, the Applicants have described two such methods:

> "...the materials collected on the filter may be prepared and examined by placing the collected material onto a slide for viewing under a microscope, or by using a Hybrid Capture™ method as described herein."

It is clear that the term "examining said collected material" is not vague or indefinite.

The Examiner then states that "...there are no steps presented in the claims that define what such examination or analysis of biological sample entail." The Applicants disagree that it is necessary that such detailed steps be presented in the claims. The essential question under 35 U.S.C. 112, second paragraph, is whether the claims set out a particular area with a reasonable degree of precision and particularity. Definiteness of claim language is analyzed, not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art. *In re Moore*, 439 F.2d 1232, 169 USPQ 236 (CCPA 1971). See also MPEP 2173.02. As mentioned above, the Applicants have provided or made reference to numerous examples of methodologies and techniques for the examination or analysis of biological samples.

The Examiner further argues that the lack of description of amounts of sample filtered, virus types, and cell types, the claims are indefinite. The Applicants disagree.

Claims should not rejected as unduly broad under 35 U.S.C. 112 for non-inclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art. *In re* Skrivan, 166 USPQ 85 (CCPA 1970). It has been generally held that it is the function of the specification and not the claims to set forth practical limits of operation. *In re* Johnson, 194 USPQ 197 (CCPA 1977). The limitations cited by the Examiner, such as the

amounts of sample filtered, virus types, and cell types, would certainly be within the level of ordinary skill in the art.

Lastly, the Examiner argues that claims 1 and 14 are incomplete for omitting essential steps, in particular the steps to analyze and examine are missing. The Applicants disagree. The Applicant is puzzled as to the Examiner's statement that claims 1 and 14 lack the steps to analyze and examine the collected samples. Claim 1 recites:

> "...a method for analyzing a biological sample to detect cells infected by human papilloma virus (HPV), comprising: passing a medium containing said sample across a filter to collect material from said medium on said sample, said filter having a pore size that is greater than a dimension of a HPV particle but smaller than a dimension of a HPV infected cell; and examining said collected material to determine if HPV infected cells are present in said material." (emphasis added)

If the Examiner is arguing that the claims lack a step of examining, then this analysis is clearly mistaken. If the Examiner is arguing that specific examples of analysis or examination of collected material are needed as further limitations of the claims as essential steps, then the Applicants disagree. The Applicants should not be limited to certain technologies or methodologies for the detection of infected cells when such technologies would clearly be known to one or ordinary skill in the art. Such analysis or examination steps are not essential nor has the Examiner demonstrated why such steps would render the claims incomplete.

Accordingly, for the reasons stated above, the rejections under 35 U.S.C. § 112, second paragraph, should be withdrawn.

The Rejections of Claims 1-3 and 14-18 Under 35 U.S.C. §112, First Paragraph Should be Withdrawn:

Claims 1-3 and 14-18 were rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. The Examiner reiterates the position that the Applicants have not provided "...how to detect or analyze the cells. The Applicants respectfully disagrees.

As mentioned above, claims should not be rejected under 35 U.S.C. 112 for non-inclusion of limitations dealing with factors which must be presumed to be within the level of ordinary skill in the art. *In re* Skrivan, 166 USPQ 85 (CCPA 1970). The limitation cited by the Examiner, such as a method for analyzing cells for the detection of cells infected with viral particles, would certainly be within the level of ordinary skill in the art. The Examiner then proceeds to reiterate objections, detailed in the previous section, of a lack of description in the specification of limitations such as sample size, filter pore size and virus type. Again, the Applicants believe that the Examiner is asking for the inclusion of limitations into the application of methodologies and technologies which clearly would be within the level of ordinary skill in the art.

It appears that the Examiner does not under stand the purpose of the Applicant's disclosure. The Examiner asks the fundamental question of "how does utilization of a cell filtration system relate to detection of infected virus?" To answer the question, one would only need to go to the background section of the Applicant's specification to find the following statement:

> "Therefore, in a diagnostic procedure, it would be desirable to prepare a sample such that it contains no or a fewer number of extracellular HPV, and to base a diagnostic result on such prepared sample. Thus, the determination of HPV cells will correlate more closely with a diagnosis of LGSIL than with a diagnosis of "Within Normal Limits" (WNL)."

Thus, the filter system of the Applicant's invention allows a practitioner to answer the question of where or not a sample taken from a patient contains cells infected with a virus. If cells are not infected, then extracellular viral particles would be washed through the filter leaving uninfected cells. The practitioner can then methods and techniques standard to one of ordinary skill in the art, to determine if the cells are indeed, free of virus. As mentioned previously, such methods were detailed by the Applicants in the specification. Such examples include morphological examination of cells under a microscope, in situ hybridization using probes or primers for viral sequences, and commercially available reagents for the detection of viruses, such as HPV. Thus, the Applicants have clearly demonstrated a particular need for a diagnostic method to distinguish infected from non-infected cells and have clearly provided sufficient teaching for a method for analyzing a biological sample to detect cells infected by a virus.

The Examiner then suggests that the Applicants have merely provided an invitation to experiment. As the court stated in Wands 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), "[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed . . . ." Id., quoting In re Jackson, 217 USPQ 804, 817 (Bd. App. 1982) (emphasis added).

The Applicant has provided sufficient guidance with respect to a method for analyzing a biological sample to detect cells infected by a virus. One skilled in the art would be able to routinely filter biological specimens through a filter which retains cells but allows for extracellular viruses to pass through and then test those remaining cells to see if any are infected. All of these steps outlined by the Applicant can be completed without undue experimentation. Accordingly, for all of the reasons stated above, the rejections under 35 U.S.C. § 112, first paragraph should be withdrawn.

The Rejection Under 35 U.S.C. § 102(e) Should Be Withdrawn

In the Office Action, claims 1-3 and 14-18 were rejected under 35 USC §102(e) as being unpatentable with respect to U.S. Patent No. 6,905,594 to Ferguson.

In the Office Action, it is asserted that the patent to Ferguson discloses a method of capturing materials suspended in a liquid utilizing a filter apparatus. The examiner also states that Ferguson does not teach a pore size for the filter however the pore size is "...a design choice unless the proof is critically proven." (see page 6 of the Office Action). The Applicants respectfully disagree.

The patent to Ferguson does not contemplate a method for the separation of viral particles from cells. Nowhere in Ferguson can the Examiner point to such a statement or teaching. The Examiner states that the pore size is a design choice, however, such a pore size is critical for the method step to work properly. A filter that has too large a pore size will allow cells to pass through the filter. A filter with to small a pore size would prevent viral particles from passing through the filter and thus a practitioner would not be able to differentiate between viral particles

which have infected cells and those particles which are extracellular. Ferguson never teaches or discloses how to make, or how to use, or how to test for the presence or absence of cells infected with a virus – in fact, Ferguson never teaches or discloses that a skilled artisan would ever need or want to make such a determination.

Therefore, contrary to the position taken in the Office Action, the Patent to Ferguson does not teach all the limitations of the claims of the present invention. Withdrawal of the rejection is requested.

The Rejection Under 35 U.S.C. § 102(b) Should Be Withdrawn

In the Office Action, claims 1-3 and 14-18 were rejected under 35 USC §102(b) as being unpatentable with respect to U.S. Patent No. 5,942,700 to Radcliffe *et al.*

In the Office Action, it is asserted that the patent to Radcliffe *et al.* discloses a method of collecting samples including biological samples through a filter. The examiner also states that the recitation of biological samples "...broadly incorporates virus and papillomavirus." (see page 7 of the Office Action). The Applicants respectfully disagree.

The patent to Radcliffe *et al.* does not contemplate a method for the separation of viral particles from cells. Nowhere in Radcliffe *et al.* can the Examiner point to such a statement or teaching. Radcliffe *et al.* never teaches or discloses how to make, or how to use, or how to test for the presence or absence of cells infected with a virus – in fact, Radcliffe *et al.* never teaches or discloses that a skilled artisan would ever need or want to make such a determination.

Therefore, contrary to the position taken in the Office Action, the patent to Radcliffe *et al.* does not teach all the limitations of the claims of the present invention. Withdrawal of the rejection is requested.

CONCLUSION

For all of the above-discussed reasons, Applicant respectfully submits that claims 1-3 and 14-18 are allowable and that the application is now in condition for allowance. A notice to this effect is earnestly solicited. It is believed that no fee is required for this submission. If any fees are required or if an overpayment is made, the Commissioner is authorized to debit or credit our Deposit Account No. 502855, accordingly. If any questions or issues remain, the resolution of which the Examiner feels would be advanced by a conference with Applicant, the Examiner is invited to contact Applicant's attorney at the number noted below.

Respectfully submitted,

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